

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/728,521-Conf. #8270
				Filing Date	December 5, 2003
				First Named Inventor	Atul Varadhachary
				Art Unit	1656
				Examiner Name	C. M. Kam
Sheet	1	of	4	Attorney Docket Number	HO-P02703US2

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				
/CMK	AA*	US-4,977,137		12-11-1990	Nichols et al.	
	AB*	US-5,198,419		03-30-1993	Ando et al.	
	AC*	US-5,457,093		10-10-1995	Cini et al.	
	AD*	US-5,561,109		10-01-1996	Mita et al.	
	AE*	US-5,571,691		11-05-1996	Conneely et al.	
	AF*	US-5,571,896		11-05-1996	Conneely et al.	
	AG*	US-5,571,697		11-05-1996	Conneely et al.	
	AH*	US-5,576,299		11-19-1996	Ando et al.	
	AI*	US-5,766,939		06-16-1998	Conneely et al.	
	AJ*	US-5,834,424		11-10-1998	Valenti et al.	
	AK*	US-5,849,881		12-15-1998	Conneely et al.	
	AL*	US-5,955,316		09-21-1999	Conneely et al.	
	AM*	US-6,025,326		02-15-2000	Steinberg, et al.	
	AN*	US-6,066,469		05-23-2000	Kruzel et al.	
	AO*	US-6,080,559		06-27-2000	Conneely et al.	
	AP*	US-6,096,731		08-01-2000	McDonald	
	AQ*	US-6,100,054		08-08-2000	Conneely et al.	
	AR*	US-6,111,081		08-29-2000	Conneely et al.	
	AS*	US-6,228,614		05-08-2001	Conneely et al.	
	AT*	US-6,333,311		12-25-2001	Nuijens et al.	
	AU*	US-6,399,570		06-04-2002	Mann	
	AV*	US-6,635,447		10-21-2003	Conneely et al.	
	AW*	US-20020016289		02-07-2002	Conneely	
	AX*	US-2003/0096736-A1		05-22-2003	Kruzel et al.	
	AY*	US-2003/0105006-A1		06-05-2003	Mann	
	AZ*	US-2003/0190303-A1		10-09-2003	KIMBER et al.	
	AA1*	US-2003/0203839-A1		10-30-2003	Kruzel et al.	
	AB1*	US-2004/0009896-A1		01-15-2004	Glynn et al.	
	AC1*	US-2004/0009895-A1		01-15-2004	Varadhachary et al.	
	AD1*	US-2004/0082504-A1		04-29-2004	Varadhachary et al.	
	AE1*	US-2004/0142037-A1		07-22-2004	Engelmayer et al.	
	AF1*	US-2004/0151784-A1		08-05-2004	Varadhachary et al.	
	AG1*	US-2004/0152624-A1		08-05-2004	Varadhachary et al.	
	AH1*	US-2004/0152623-A1		08-05-2004	Varadhachary et al.	
	AI1*	US-2004/0176276-A1		09-09-2004	Varadhachary et al.	
	AJ1*	US-2005/0004006-A1		01-06-2005	Engelmayer et al.	
	AK*	US-2005/0019342-A1		01-27-2005	Varadhachary et al.	
	AL*	US-2005/0064546-A1		03-24-2005	Conneely et al.	
/CMK	AM*	US-2005/0075277-A1		04-07-2005	Varadhachary et al.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ² -Number ⁴ -Kind Code ³ (if known)					
Examiner Signature		/Chih-Min Kam/			Date Considered	06/30/2007	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/728,521-Conf. #8270
				Filing Date	December 5, 2003
				First Named Inventor	Atul Varadhachary
				Art Unit	1656
				Examiner Name	C. M. Kam
Sheet	2	of	4	Attorney Docket Number	HO-P02703US2

/CMK/	BA	WO-9221752	12-10-1992	The United States of America		
	BB	EP-0584558	03-02-1994	Snow Brand Milk Prod Co Ltd		
	BC	JP-07233086	09-05-1995	Morinaga Milk Industry Co Ltd		
	BD	EP-0730868	09-11-1996	Tamotsu Satch		
	BE	WO-9833509	08-06-1998	Pharming Intellectual Property Bv		
	BF	WO-0203910-A2	01-17-2002	Yakubovskaya Ralsa Ivanovna et al.		
/CMK/	BG	WO-02100445-A1	12-19-2002	The University of Sydney		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ²
/CMK/	CA	ARNOLD et al, "Bactericidal Activity of human Lactoferrin: Sensitivity of a Variety of Microorganisms," Infection and Immunity Vol. 28, No. 3, June 1980, pgs 893 - 898.				
	CB	ARTYM et al, "Lactoferrin Restoration of Lymphocyte and Macrophage Content in Cyclophosphamide-Treated mice," Cellular & Molecular Biology Letters Vol. 7, Sept. 2002, pg 37.				
	CC	ARTYM et al, "Normalization of Peripheral Blood Cell Composition by Lactoferrin in Cyclophosphamide-treated Mice," Med Sci Monit. Vol. 10 No. 3, 2003, pgs BR84-89.				
	CD	ARTYM et al, "Orally Administered Lactoferrin Restores Humoral Immune Response in Immunocompromised Mice," Immunology Letter Vol. 89, 2003, pgs. 9 -15.				
	CE	ARTYM et al, "Reconstitution of the Cellular Immune Response by Lactoferrin in Cyclophosphamide-treated mice is Correlated with Renewal of T Cell compartment," Immunobiol. Vol. 207, 2003, pgs 197-205.				
	CF	BELLAMY et al, "Killing of Candida Albicans by lactoferrin B, a Potent Antimicrobial Peptide derived from the N-terminal Region of Bovine Lactoferrin," Med Microbial Immunol. Vol. 182, 1993, pgs 97 - 105.				
	CG	BRINK, "Lactoferrin: The Bioactive Peptide that Fights Disease," Life Extension Magazine, found at http://www.lef.org/LEFCMS/asp/PringVersionMagic.aspx?CmsID=31812 , October, 2000.				
	CH	CLARKE et al, "Evaluation of Bovine Lactoferrin as a Topical Therapy for Chemotherapy-Induced Mucositis in the Golden Syrian Hamster," Oral Oncology 35, 1999, pp. 197-202.				
	CJ	CUMBERBATCH et al, "IL-1 B-induced Langerhans' cell Migration and TNF-A production in Human Skin: Regulation by Lactoferrin," Clin Exp. Immunol 132, 2003, pp. 352-359.				
	CK	CUMBERBATCH et al, "Regulation of Epidermal Langerhans Cell Migration by Lactoferrin," Immunology 2000, 100, pp. 21-28.				
	CM	DIAL et al, "Effect of Lactoferrin of Helicobacter felis Induced Gastritis," Biochem. Cell Biol. Vol. 80, 2002, pgs 113 - 117.				
	CM1	DONNELLY, et al., Antimicrobial therapy to prevent or treat oral mucositis. Lancet Infect Dis. 2003 Jul; 3(7):405				
/CMK/	CN	ELLISON et al, "Damage of the Outer Membrane of Enteric gram-Negative Bacteria by Lactoferrin and Transferrin," Infection and Immunity Vol. 56 No. 11, November 1988, pgs 2774				

Examiner Signature	/Chih-Min Kam/	Date Considered	06/30/2007
--------------------	----------------	-----------------	------------

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/728,521-Conf. #8270
		Filing Date	December 5, 2003
		First Named Inventor	Atul Varadhachary
		Art Unit	1656
		Examiner Name	C. M. Kam
		Attorney Docket Number	HO-P02703US2
Sheet	3	of	4

		- 2781.	
/CMK	CO	FUJIHARA et al, "Lactoferrin Protects Against UV-B Irradiation-Induced Corneal Epithelial Damage in Rats," Cornea 19(2); 2000, pp. 207-211.	
	CP	HARMSEN et al, "Antiviral Effects of Plasma and Milk Proteins: Lactoferrin Shows Potent Activity against Both Human Immunodeficiency Virus and Human cytomegalovirus Replication in Vitro," Journal of Infectious Diseases Vol. 172, 1995, pgs 380 - 388.	
	CQ	HE et al, "The Inhibition of Mast Cell Activation by Neutrophil Lactoferrin: Uptake by Mast Cells and Interaction with Trypsin, Chymase and Cathepsin G," Biochemical Pharmacology 65, 2003, pp. 1007-1015.	
	CR	IKEDA et al, "Lactoferrin Markedly Inhibits Hepatitis C Virus Infection in Cultured Human Hepatocytes," Biochemical and Biophysical Research Communications Vol. 245, 1998, pgs 549 - 553.	
	CS	INOUE et al, "Colostrum and severe gut GVHD," Bone Marrow transplant Vol 22 No. 4, 1998, pgs 402- 403.	
	CT	INOUE et al, "Lactoferrin and Gut GVHD," 5th annual Conference on Lactoferrin, Banff, Canada 2001.	
	CU	ISAMIDA et al, "Protective Effect of Lactoferrin against Toxoplasma Gondii Infection in Mice," J Vet Med Sci. Vol. 60 No 2, 1998, pgs 241 - 244.	
	CV	KIMBER et al, "Lactoferrin and Regulation of Cutaneous Immunity and inflammation," Elsevier Science B.V., 2000, pgs 87-93.	
	CW	KIMBER et al, "Lactoferrin: Influence on Langerhans Cells, Epidermal Cytokines, and Cutaneous Inflammation," Biochem Cell Biol. 80, 2002, pp. 103-107.	
	CX	KUHARA, T. et al., (2000) "Orally administered lactoferrin exerts an antimetastatic effect and enhances production of IL-18 in the intestinal epithelium" Nutrition and Cancer, Vol. 28(2), pp. 192-199.	
	CY	KUIPERS et al, "Synergistic Fungistatic Effects of Lactoferrin in Combination with Antifungal Drugs against Clinical Candida Isolates," Antimicrobial agents and Chemotherapy Vol. 43, No. 11, November 1999, pgs 2635-2641.	
	CZ	LEGRAND et al, "The N-terminal Arg2, Arg3, Arg4 of Human Lactoferrin Interact with Sulphated Molecules but Not with the Receptor Present on Jurkat Human Lymphoblastic T-Cells," Biochem J Vol. 327, pp. 841-846 (1997).	
	CA1	LEVAY et al, "Lactoferrin: A General Review," Haematologica Vol. 80, 1995, pgs 252-267.	
	CB1	MAKKONEN, et al., Granulocyte macrophage; Int. J. Radiation Oncology; Biol. Phys.; 2000; Vol. 46 (3); 525-534.	
	CC1	MARCHETTI et al, "Metal Complexes of Bovine Lactoferrin Inhibit in vitro Replication of Herpes Simplex Virus Type 1 and 2," BioMetals Vol. 11, 1998, pgs 89-94.	
	CD1	MASSON et al, "Lactoferrin in Milk from Different Species," Comp. Biochem. Physiol. Vol. 39B, 1971, pgs 119 -129.	
		MATTHEWS et al, "Antiviral Activity in milk of Possible Clinical Importance," The Lancet, December 1976, pgs 1387 - 1389.	
	CE1	METZ-BOUTIGUE et al., "Human Lactotransferrin: Amino Acid Sequence and Structural Comparisons with other transferrins," Eur J. Biochem. Vol. 145, 1984, pgs 659 - 676.	
	CF1	MIEHLKE et al, "Direct Activity of recombinant Human Lactoferrin against Helicobacter Pylori," Journal of Clinical Microbiology, Oct. 1996, pgs 2593 - 2594.	
	CG1	NAKAJIMA et al, "Lactoferrin as a Suppressor of Cell Migration of Gastrointestinal Cell Lines," Journal of Cellular Physiology 170, 1997, pp. 101-105.	
/CMK	CH1	SATO et al, "Oral Administration of Bovine Lactoferrin for Treatment of Intractable Stomatitis in Feline Immunodeficiency Virus (FIV)-positive and FIV-negative Cats," AJVR Vol. 57 No. 10,	

Examiner Signature	/Chih-Min Kam/	Date Considered	06/30/2007
--------------------	----------------	-----------------	------------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/728,521-Conf. #8270
				Filing Date	December 5, 2003
				First Named Inventor	Atul Varadhachary
				Art Unit	1656
				Examiner Name	C. M. Kam
Sheet	4	of	4	Attorney Docket Number	HO-P02703US2

		October 1996, pgs 1443 - 1446.	
/CMK/	CI1	SHIH, et al., A Research Review of the Current Treatments for Radiation, Oncology Nursing Forum; August 2002, Vol. 29 (7); 1063-1080.	
	CJ1	TAKAKURA et al, "Effect of Orally Administered Bovine Lactoferrin on the immune Response in the Oral Candidiasis Murine Model," J Med Microbiol Vol 53, Pt. 6, Jun 2004, pgs 495-500.	
	CK1	TAKAKURA et al, "Oral Lactoferrin Treatment of Experimental Oral Candidiasis in Mice," Antimicrobial Agents and Chemotherapy Vol. 47 No. 8, August 2003, pgs. 2619-2623.	
	CL1	TAKAYAMA et al, "Effects of Lactoferrin on Collagen Gel Contractile Activity and Myosin Light Chain Phosphorylation in Human Fibroblasts," FEBS Letter 508, 2001, pp. 111-116.	
	CL2	TAKAYAMA et al, "The Bovine Lactoferrin Region Responsible for Promoting the Collagen Gel Contractile activity of Human Fibroblasts," Biochemical and Biophysical Research Communications 299 (2002), pp 813-817.	
	CM1	TOMITA et al, "Potent Antibacterial Peptides Generated by Pepsin Digestion of Bovine Lactoferrin," J Dairy Sci Vol. 74, 1991, pgs 4137 - 4142.	
	CN1	TRUMPLER et al, "Antibacterial Prophylaxis with Lactoferrin in Neutropenic Patients," Eur. J. Clin. Microbiol. Infect. Dis. Vol. 8, no. 4, 1989, pgs 310 - 313.	
	CO1	VAN BERKEL et al, "N-terminal Stretch Arg2, Arg3, and Arg5 of Human Lactoferrin is Essential for Binding to Heparin, Bacterial Lipopolysaccharide, Human Lysozyme and DNA," Biochem J. Vol. 328, pp. 145-151 (1997).	
	CP1	VORLAND et al, "Lactoferrin: A Multifunctional Glycoprotein," APMIS Vol. 107, 1999, pgs. 971 -981.	
	CQ1	WARD et al, "A System for Production of Commercial Quantities of Human Lactoferrin: A Broad Spectrum Natural Antibiotic," Biotechnology Vol. 13, may 1995, pgs 498 - 503.	
	CR1	WARD et al, "Lactoferrin and Host Defense," Biochem Cell Biol. 80, 2002, pp. 95-102.	
	CS1	WEINBERG, Eugene, "The Therapeutic Potential of Lactoferrin," Expert Opinion Investig. Drugs, 12(5), 2003, pp. 841-851.	
	CT1	YAMAGUCHI et al, "Potential Usefulness of Bovine Lactoferrin for Adjunctive Immunotherapy for Mucosal Candida Infections," Biometals Vol. 17 No. 3, June 2004, pgs 245 - 248.	
	CU1	YANG et al, "Antitumor Activity and Specificity as a Function of Substitutions in the Lipophilic Sector of Helical Lactoferrin-derived Peptide," Journal of Peptide Science 9, 2003, pp. 300-311.	
/CMK/	CV1	YANG et al., "Enhanced Antitumor Activity and Selectivity of Lactoferrin-derived peptides," J. Peptide Res. 60, 2002, pp. 187-197.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Chih-Min Kam/	Date Considered	06/30/2007
--------------------	----------------	-----------------	------------